Public consultation 'Introduction of fees to be charged by the EMA for pharmacovigilance' - Comments from the Medicines Evaluation Board, the Netherlands

Introduction

The Medicines Evaluation Board (MEB) welcomes the introduction of fees to be charged for pharmacovigilance activities. The principal of charging fees for those activities is endorsed by the MEB. Whereas the pharmacovigilance legislation already went into force last July 2012, the MEB urges the European Commission not to loose pace and come with a simple model for EMA to charge fees. The structure to raise fees for pharmacovigilance activities should not become complex, to avoid that levying fees will be extremely administrative (therefore costly for the EMA) and to avoid the creation of another administrative burden or financial hurdle for the Marketing Authorisations Holders to accomplish the regulation.
Post approval activities are legally imposed (for example to include extra safety data) to guarantee public health and should always be levied objectively. Therefore the MEB would prefer *one annual fee* instead of 4 different types of fees for various assessment procedures.

A simple and transparent fee structure should compensate an equitable proportion of the work provided by the National Competent Authorities. In the outline of the general principles in proposing fees, the remuneration of the work/tasks performed by the National Competent Authorities is briefly touched upon, however it is not reflected in the different types of proposed fees. The Marketing Authorisation Holder pays for a service which is provided by the EMA, but based on the expertise of the NCAs. The MEB would like to emphasize that all the assessments are done on the basis of the scientific resources and the expertise of the National Competent Authorities of the EU which should be reflected clearly in the fee regulation.

Comments on the consultation

Whereas the MEB would prefer an annual fee, this response draws upon the proposed fees for several pharmacovigilance activities. Furthermore, the financial explanation on workload and how this will cover costs resulting from requires clarification. Especially the ranging of fees and the additional charge of 500€ needs further justification.

3.1 Fee for assessments of PSURs

However if the regulation will foresee a different type of fees for the assessment of PSURs, the MEB is of the opinion that one *fee should be charged for each assessment of a PSUR based on the frequency*. One fee is favourable due to the fact that the amount of work is not to be foreseen and to avoid administrative burden installed to levy the fees for different types/different intervals of PSURs. Fees should always be raised objectively and the system should elude every assumption that there is a financial incentive to increase assessments.
The current pharmacovigilance legislation is active substance based (previously more product based) which would mean that data for PSUR assessment is submitted in one repository. In this respect one single EU assessment (by the PRAC) would involve already some kind of grouping.

3.2 Fee for assessment of PASS

The MEB would like to see the costs for the assessment of the study report for a PASS elaborated including the assumption that the assessment of a PASS involves the same amount of data to be assessed as for a type II variation. It is not clear if the fee regulation would include (besides the final report) also the preparatory or on-going work such as assessment of the study protocol, progress report etc.
In the consultation paper it is mentioned that a fee will only be levied if the PASS is imposed as part of the initial Marketing Authorisation, would this grouping involve Marketing Authorisations with the same active substances or a grouping based on the same product classes?

3.3 Fee for Assessment of Pharmacovigilance Referrals

The work for a pharmacovigilance referral has to be performed on short notice by the (co)rapporteur within the PRAC. The rapporteur and co-rapporteur have to assess in a short period of time data provide by Marketing Authorisation Holder, however without a financial clarification it is rather difficult to judge the ranging of a fee from a maximum and minimum. The MEB is in favour of an annual fee plus (in case it would occur) a separate fee for the assessment of pharmacovigilance referral charged to the Marketing Authorisation Holder.

3.4 Pharmacovigilance Service fee

As pointed out, before the MEB would like to have a pharmacovigilance service fee as an annual ‘flat’ fee for every registered product.
Which services would involve or be covered by the service fee (assessment such as RMP, signal detection, PAES etc.)? The financial context is missing and therefore challenging to oversee if this fee is proportional.

3.5 Fees and incentives for SMEs as regards pharmacovigilance

A derogation for SMEs in their kick-off towards a registration as an incentive is supported by the MEB. However if the registration is finalised, every Marketing Authorisation Holder has to fulfil all legal requirement. Thus a SME should fulfil post approval the same legal requirements as any other Marketing Authorisation Holders. A reduced fee for a SME having a CAP registered would not create an equal level playing field.

The MEB would like to emphasize that the assessment of pharmacovigilance will be done by the PRAC members (regardless if it involves a SME) who will be remunerated for their assessment and SMEs should not be exempted from the annual fee for their post approval pharmacovigilance activities.

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